

of data collected during the validation step, and

- a step of processing of ~~the data collected~~ <sup>out</sup> in the different validation steps, to issue ~~final~~ <sup>out</sup> certification (CF) of a preparation carried out according to ~~the standard operating procedure~~ <sup>indef</sup> and/or a list of the anomalies detected during this preparation.

*Sub B1*  
Claim 2 (amended) The process according to claim 1, wherein validation of the final certification is conditional on the input of a validation password with a computer.

*Cont*  
Claim 3 (amended) The process according to claim 1, implemented in a data processing system, wherein with each validation step is associated at least one screen page.

*provides what?*  
PO: the screen page which provides the process operator

PEI: screen page corresponding to a stage of process number

*i ?*  
EP: title

EA: retrospective analysis screen page

EC: certification screen page

EI: anomalies screen page

which can be accessed on a display means of at least one computer workstation connected to said data processing system.

*Sub E2*  
Claim 4 (amended) The process according to claim 3, wherein each screen page comprises a coded identification field for a patient which matches a batch of samples subjected to the standard operating procedure.

*Sub B2*  
Claim 5 (amended) The process according to claim 1 wherein

*B.2* *ant*  
the exit from certain stages (RA) of said process is conditional on printing the screen pages (EA) ~~WHICH ONES~~ corresponding to these stages.

*Sub C.17*  
Claim 6 (amended) The process according to claim 1 implemented in a preparation laboratory receiving therapeutic kits from at least one operational entity (EX), wherein it further comprises stages for monitoring the transfer of these kits.

Claim 7 (amended) The process according to claim 1 implemented in a preparation laboratory which deals with a cytapheresis service, wherein it further comprises stages for monitoring the receipt of cytapheresis pouches.

*Sub C.18*  
Claim 8 (amended) The process according to claim 1 implemented in a preparation laboratory which deals with a control laboratory, wherein it further comprises stages for processing the ~~results of control tests carried out on each batch of samples.~~ *no out*

Claim 9 (amended) A system for the processing of information used for the management of quality in a therapeutic process of claim 1 comprising:

- for each functional step, a means of sequential and conditional validation (VA) of said step, the passing from one validation step to the following validation step being conditional on the results of the processing of data collected during this validation step, and

- a means of processing of the data collected in the different validation steps, to issue final certification (CF) of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during the *und. 1*

preparation.

*Side by*  
Claim 10 (amended) A system according to claim 9, implemented in a preparation laboratory, wherein it is further designed to execute management tasks of a preparation laboratory number n within this laboratory.

*App cont*  
Claim 11 (amended) A system according to claim 9, wherein it is connected to a communications network in order to exchange data with other entities: (treatment centers number n, cytapheresis services number n, collection centers number n, bacteriological testing laboratories involved in a therapeutic process. *ALL OR SOME?*)

Claim 12 (amended) Application of the process and of the information processing system used for quality management according to claim 1 to cell therapy protocols. *no aut*

Claim 13 (amended) Application of the process and of the information processing system used for quality management according to claim 1 to gene therapy protocols. *no aut*

Claim 14 (amended) Application of the process and of the quality management system according to claim 1, allowing ongoing training of the operator and/or the monitoring of his or her level of knowledge. *no aut*

#### REMARKS

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 1 to 14. With